



Practitioner's Docket No. U 016095-7

PATENT

3738

IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

of

Inventor(s)

for

Title of invention

OR

In re application of: Ehud SCHWAMMENTHAL, et al.

Serial No.: 10/563,384

Group No.:

Filed: April 20, 2006

Examiner:

For: IMPLANTABLE PROSTHETIC DEVICES PARTICULARLY FOR TRANSARTERIAL DELIVERY IN THE TREATMENT OF AORTIC STENOSIS, AND METHODS OF IMPLANTING SUCH DEVICES

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
WITHIN THREE MONTHS OF FILING OR
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. 1.97(b))

CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10*

(When using Express Mail, the Express Mail label number is **mandatory**;
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

- ☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

37 C.F.R. 1.8(a)

37 C.F.R. 1.10*

- ☒ with sufficient postage as first class mail.

- ☐ as "Express Mail Post Office to Addressee"
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TRANSMISSION

- ☐ transmitted by facsimile to the Patent and Trademark Office, to (571)-273-8300

Date: October 11, 2006

Signature
Clifford J. Mass

(type or print name of person certifying)

* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

NOTE: 37 C.F.R. 1.98(b):

- (1) Each U.S. patent listed in an information disclosure statement must be identified by inventor, patent number, and issue date.
- (2) Each U.S. patent application published listed in an information disclosure statement shall be identified by applicant, patent application publication number, and publication date.
- (3) Each U.S. application listed in an information disclosure statement must be identified by the inventor, application number, and filing date.
- (4) Each foreign patent or published foreign patent application listed in an information disclosure statement must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application.
- (5) Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.

WARNING: No extension of time can be had under 37 C.F.R. § 1.36 (a) or (b) for filing an IDS. 37 C.F.R. § 1.97(f).

NOTE: The "filing date of a national application" under 37 C.F.R. 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark office, the filing is defined in 37 C.F.R. 1.53(b) as "the date on which: (1) A specification containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75; and (2) any drawing required by § 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by § 1.41." 37 C.F.R. 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. § 371(c) within the periods set forth in § 1.494 or § 1.495. 35 U.S.C. § 371(c) requires the filing of the following: (1) the national fee; (2) a copy of the international application, unless already sent by the International Bureau, and an English translation if filed in another language; (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. 37 C.F.R. 1.97(b)(2).

IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. 1.97(b).

NOTE: "No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."

NOTE: "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 C.F.R. 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

WARNING: "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63). But see § 103(b) and (c), limited suspension of action in a continued prosecution application (CPA) filed under § 1.53(d) and in a request for continued examination (RCE) under § 1.114.

If a fee is required, please charge deposit account 12-0425.

Reg. No.

Tel. No.: ()

Customer No.:



SIGNATURE OF PRACTITIONER

Clifford J. Mass, 30086, (212) 708-1890
(type or print name of practitioner)

P.O. Address

c/o Ladas & Parry LLP
26 West 61st Street
New York, N.Y. 10023



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Application of:

Ehud SCHWAMMENTHAL, et al.

Serial No.: 10/563,384

Filed: April 20, 2006

For: IMPLANTABLE ROSTHETIC DEVICES
PARTICULARLY FOR
TRANSARTERIAL DELIVERY IN THE
TREATMENT OF AORTIC STENOSIS,
AND METHODS OF IMPLANTING
SUCH DEVICES

) Art Unit: 3738

) Examiner: (N/A)

) Washington, D.C.

) August 15, 2006

) Docket No.: U 016095-7

INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

☒ 1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:

(Check one of the boxes A-D)

☐ A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.

☒ B. before the mailing date of a first office action on the merits.

☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below).

(check one of the boxes "i" and "ii" below:)

☐ i. Counsel certifies that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

☐ ii. A check for the fee set forth in 1.17(p), presently believed to be \$240, is enclosed (check no. _____).

☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant petitions under 37 C.F.R. 1.97(d) for the consideration of this IDS. A check for the fee set forth in §1.17(i), presently believed to be \$130 is enclosed (check no. _____). Counsel certifies that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

☒ 2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A and/or B and fill in blanks, if appropriate.)

☐ A. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.

☐ B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

[insert serial numbers and filing dates of prior applications]

Applicant identifies these documents by attaching hereto copies of the forms PTO-892 and PTO-1449 from the files of the prior application(s) or a fresh PTO-1449 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

☐ 3. Documents ____ is (are) not in the English language. In accordance with 1.98(c), Applicant states:

☐ An English translation of each document _____ (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.

☐ A concise explanation of the relevance of document(s) _____ is found in the attached search report (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).

☐ A concise explanation of the relevance of document(s) _____ is set forth as follows:
[Insert concise explanation of relevance]

☐ A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.

☐ A concise explanation of document(s) _____ can be found on the attached sheet.

4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

☐ 5. Other information being provided for the examiner's consideration follows:

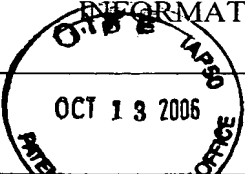
6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

CROSS REFERENCE UNDER 37 C.F.R. §1.78 TO RELATED APPLICATIONS

Pursuant to 37 C.F.R. § 1.78, Applicant notes that the above-identified patent application may be related to the following U.S. Patent Applications:

Respectfully submitted,

Clifford J. Mass
c/o Ladas & Parry LLP
26 West 61st Street
New York, New York 10023
Reg. No. 30086
Tel. No. (212) 708-1890

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| FORM PTO-1449 (Colb) | ATTY DOCKET NO. U 016095-7 | SERIAL NUMBER 10/563,384 |
| LIST OF PATENTS AND PUBLICATIONS FOR APPLICANTS' INFORMATION STATEMENT | APPLICANT Ehud SCHWAMMENTHAL, et al. | EXAMINER (N/A) |
|  | FILING DATE April 20, 2006 | GROUP ART UNIT 3738 |

U.S. PATENT DOCUMENTS

| Examiner's Initials | | DOCUMENT NO. | DATE | NAME | CLASS | SUB | FILING DATE |
|------------------------|----|--------------|---------|----------------|-------|-----|----------------|
| | AA | 4,491,986 | 01/1985 | Gabbay | | | |
| | AB | 5,344,442 | 09/1994 | Deac | | | |
| | AC | 5,908,451 | 06/1999 | Yeo | | | |
| | AD | 6,312,465 | 11/2001 | Griffin | | | |
| | AE | 6,458,153 | 10/2002 | Bailey | | | |
| | AF | 7,018,408 | 03/2006 | Bailey | | | |
| | AG | 2004/0210304 | 10/2004 | Seguin et al. | | | |
| | AH | 5,354,330 | 10/1994 | Hanson, et al. | | | |
| | AI | 5,178,632 | 01/1993 | Hanson | | | |
| | AJ | 4,078,268 | 03/1978 | Possis | | | |

FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NO. | DATE | COUNTRY | CLASS | SUB | TRANS- LATION |
|--|----|--------------|---------|---------|-------|-----|------------------|
| | AK | WO 05/002466 | 01/2005 | WIPO | | | |

OTHER ART (Including Author, Bills, Pertinent Pages, Etc.)

| | | |
|--|----|--|
| | AL | U.S. Provisional Patent Application Number 60/530,781. |
| | AM | U.S. Provisional Patent Application Number 60/465,141. |

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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U.S. PATENT DOCUMENTS

| Examiner's Initials | | DOCUMENT NO. | DATE | NAME | CLASS | SUB | FILING DATE |
|------------------------|----|--------------|---------|------------------|-------|-----|----------------|
| | AA | 4,846,830 | 07/1989 | Knoch, et al. | | | |
| | AB | 5,108,425 | 04/1992 | Hwang | | | |
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| | AD | 6,454,799 | 09/2002 | Schreck | | | |
| | AE | 6,830,584 | 12/2004 | Seguin | | | |
| | AF | 5,840,081 | 11/1988 | Andersen, et al. | | | |
| | AG | 6,168,614 | 01/2001 | Andersen, et al. | | | |
| | AH | 5,332,402 | 07/1994 | Teitelbaum | | | |
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| | AK | | | | | | |

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| | | |
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| | AL | Heinrich RS et al., Ann Biomed Eng. 1996 Nov-Dec;24(6):685-94. Experimental analysis of fluid mechanical energy losses in aortic valve stenosis: importance of pressure recovery. |
| | AM | Marcus RH et al., Circulation. 1998 Sep 1;98(9):866-72. Assessment of small-diameter aortic mechanical prostheses: physiological relevance of the Doppler gradient, utility of flow augmentation, and limitations of orifice area estimation. |

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| Examiner's Initials | | DOCUMENT NO. | DATE | NAME | CLASS | SUB | FILING DATE |
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| | AC | 7,018,406 | 03/2006 | Seguin, et al. | | | |
| | AD | 2002/0186558 | 12/2002 | Plank et al. | | | |
| | AE | 2003/0171805 | 09/2003 | Berg | | | |
| | AF | 2003/0023300 | 01/2003 | Bailey | | | |
| | AG | 2004/0186563 | 09/2004 | Lobbi | | | |
| | AH | 2003/0130729 | 07/2003 | Paniagua, et al. | | | |
| | AI | 2005/0075720 | 04/2005 | Nguyen, et al. | | | |
| | AJ | 2006/0058872 | 03/2006 | Salahieh, et al. | | | |

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| AL | PD Stein et al., Circulation Research, Vol 39, 5 8-65, 1976 by American Heart Association. Turbulent blood flow in the ascending aorta of humans with normal and diseased aortic valves. |
| AM | Weyman AB et al., Rev Cardiovasc Med. 2005;6(1)23-32. Aortic Stenosis: Physics and Physiology-What Do the Numbers Really Mean? |
| EXAMINER: _____ DATE CONSIDERED: _____ | |
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|------------------------|----|--------------|---------|-------------------|-------|-----|----------------|
| | AA | 2005/0137688 | 06/2005 | Salahieh, et al. | | | |
| | AB | 2005/0137690 | 06/2005 | Salahieh, et al. | | | |
| | AC | 2005/0137691 | 06/2005 | Salahieh, et al. | | | |
| | AD | 2005/0197695 | 09/2005 | Stacchino, et al. | | | |
| | AE | 2005/0240200 | 10/2005 | Bergheim | | | |
| | AF | 2006/0025857 | 02/2006 | Bergheim, et al. | | | |
| | AG | 2006/0025855 | 02/2006 | Lashinski, et al. | | | |
| | AH | 6,458,153 | 10/2002 | Bailey, et al. | | | |
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| AL | Deac RF et al., Ann Thorac Surg. 1995 Aug;60(2 Suppl):S433-8. New evolution in mitral physiology and surgery: mitral stentless pericardial valve. |
| AM | Heinrich RS et al., J Heart Valve Dis. 1999 Sep;8(5):509-15. Valve orifice area alone is an insufficient index of aortic stenosis severity: effects of the proximal and distal geometry on transaortic energy loss. (an abstract). |

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| | AA | 2004/0106976 | 06/2004 | Bailey, et al. | | | |
| | AB | 2004/0059429 | 03/2004 | Amin, et al. | | | |
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| | AD | 6,076,742 | 06/2000 | Benary | | | |
| | AE | 5,964,405 | 10/1999 | Benary, et al. | | | |
| | AF | 2004/0260389 | 12/2004 | Case | | | |
| | AG | 6,682,559 | 01/2004 | Myers | | | |
| | AH | 2005/0182483 | 08/2005 | Osborne | | | |
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| | AA | 2002/0026233 | 02/2002 | Shaknovich | | | |
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